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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,027	02/17/2004	John H. Shaddock	9222.17800-DIV 2	9263

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EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/780,027	SHADDUCK, JOHN H.	
	Examiner	Art Unit	
	Ahmed M Farah	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/17/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: the abstract of contains more than 150 words.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by

Edwards U.S. Patent No. 6,092,528.

Edwards discloses apparatus and methods of use for treating a selected wall region **12** of an esophagus, comprising: introducing an elongate member **18** into the esophagus, the elongate member comprising at least one electrode **22** operatively coupled to a source of radio-frequency energy, and an inflatable/expandable member **24** carried by the elongate member, wherein the expandable member stabilizes the electrode in physical and electrical contact with the selected wall region while being free of physical or electrical contact with electrode. In this Office Action, the word 'inflate' is defined as to "enlarge or amplify," see the footnote ¹.

As to the limitation that the expandable member is not in physical or electrical contact with the electrode, Fig. 8B of Edwards shows that there is an insulation layer **68** between the expandable member **24** and the exposed segment **72** of the electrode. Therefore, the expandable member is free of physical and/or electrical contact with the working end of the electrode.

As to claims 3-6 and 13-17, Edwards teaches that "it is desirable to deliver sufficient energy to the targeted treatment site **12** to be able to achieve tissue temperatures in the range of 55-950C." *see col. 9, lines 50-55*. Hence, he anticipates the recited limitations.

As to claims 7, 8, 17 and 18, Edwards clearly modulates the power level of the RF energy delivered to the tissue in response to a measured temperature of the tissue being treated. *See col. 11, lines 23-36*.

¹ The American Heritage Dictionary of the English Language, Third Edition copyright 1992 by Houghton Mifflin Company (*in·flate* (in-flāt') *verb*, *in·flat·ed*, *in·flat·in*: To enlarge or amplify unduly).

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4. Claims 1, 2, 7-12, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Laufer et al. U.S. Pat. No. 6,033,397.

As to claims 1 and 9, Laufer et al. disclose apparatus and methods for the treatment of esophageal varices using RF energy, the apparatus comprising:

a catheter **10** (elongated member), which has at least one electrode **12** at its working end **11** to deliver RF to treat tissue in selected wall region of an esophagus; and an inflatable balloon **40** (inflatable body) carried by the catheter **10** to stabilize the energy delivery electrodes **12** in physical and electrical contact with the tissue being treated, the inflatable balloon being free of physical or electrical contact with the energy delivery electrodes **12**. See *Fig. 9; column 4, lines 46-49; and column 12, lines 56-66*.

As to claims 2, 11, and 12, they teach that as the RF energy is applied to the electrodes, the surrounding tissue becomes heated and begins to shrink. See *the abstract and column 8, lines 54-61*.

As to claims 7, 8, 17 and 18, they measure the temperature and the impedance of the tissue being treated and in turn modulate the power level of the electrical energy irradiated towards the tissue. See *column 9, lines 57-65 and column 11, lines 19-61*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claims 38-41 and 48-51 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Laufer et al. in view of Farley et al. U.S. Pat. No. 6,401,719 B1 and Edwards U.S. Pat. No. 6,092,528.

Although Laufer et al., described above, teach that the application of the RF energy is halted when the temperature of the tissue reaches or exceeds at certain levels (column 12, lines 3-6), they do not specifically describe the suitable temperature ranges in which the tissue is subjected to during the treatment.

However, Farley et al. teach an alternative apparatus to treat tissue in selected wall region of an esophagus using RF energy wherein the tissue is heated up to 70⁰ C. and higher (see *column 13, lines 14-24*). Edwards, described above, teaches that it is desirable to deliver sufficient energy to the targeted treatment site to be able to achieve tissue temperatures in the range of 55-95⁰C.

Thus, it would have been obvious to one skilled in the art the time of the applicant's invention to modify Laufer et al. in view of Farley et al. and in view of Edwards and use the temperature ranges between 45⁰ C to 70⁰ C order to shrink the esophagus tissue without causing damage to the tissue.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following references:

U.S. Patent No. 6,073,052 to Zelickson et al. discloses a device and method for the treatment of gastroesophageal reflux disease, the apparatus comprising an elongate member, the elongate member comprising an inflatable balloon **20A** and energy delivery electrodes **16A** disposed on the outer surface of the balloon, wherein the balloon stabilizes the energy delivery electrodes on the treatment site.

U.S. Patent No. 5,776,176 to Rudie and U.S. Patent No. 4,295,464 to Shihata, respectively, disclose a catheter device in which at least one inflatable member is disposed on its working end so as to stabilize the catheter on a desired treatment site.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M Farah whose telephone number is (703) 305-5787. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM on every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M DVorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should


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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Farah,
Primary examiner, AU: 3739


12/25/2004